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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,407	09/01/2004	Jocelyne Franchi	26274	8362

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

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07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,407	FRANCHI ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-66 and 84* is/are pending in the application.

4a) Of the above claim(s) *36-39 and 45-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35,40-44 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of March 13, 2009 made to the office action filed November 14, 2008. Claims 31-66 and 84 are pending. Claims 67-83 are cancelled, and claims 36-39 and 45-66 are withdrawn.

In light of the Applicant's arguments and amendments all previous 35 U.S.C. 103(a) rejections are withdrawn. Particularly the cancellation of claims 67-83 and the teachings of Jackson et al. facilitated the withdrawal of the previous claims. More specifically, Jackson et al. teach that compositions comprising phytosphingosine and derivatives thereof increase the lipid materials in the stratum corneum of the skin (see column 1, lines 4-10 and column 3, lines 39-43), whereas the Applicant has shown that the combination of phytosphingosine and Coleus lead to a powerful reduction in the fat store (see page 20, figure 6).

Due to the Applicant's arguments were found persuasive, the new 35 USC 112 rejection is made below, thus constituting a NEW NON-FINAL rejection. Applicant's arguments with respect to claim have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

The Examiner attempted several times to reach an agreement to amend the claims to the following allowable matter, but the Applicant's found the amendments unacceptable.

The proposed amendments are as follows:

1. In claim 31, line 3, after "slimming effect of a" insert "composition comprising a", further in line 5, after "thereof" insert "in a concentration of between 0.001% and 1% by weight with respect to the total weight of said composition; further comprising at least one cosmetically acceptable lipolytic agent selected from the group consisting of forskolin and plant extracts containing the same in a concentration of between 0.001% and 1% by weight with respect to the total weight of said composition, wherein said forskolin and plant extracts containing the same is selected from the group consisting of extracts of Coleus forskohlii and Plectranthus barbatus".

2. Cancel 34-66.

The following is an examiner's statement of reasons for allowance: the claims 31-35, 40-43 and 84 are drawn to a method of cosmetic care for obtaining a slimming effect on the human body comprising the topical application of a composition comprising

at least one phytophingosine and extracts of Coleus forskohlii or Plectranthus barbatus. There is no prior art disclosing the applicant's combination that provides a "slimming effect". Both phytophingosine and enzyme adenylate cyclase compounds from plant extracts are known to provide anti-aging effects as taught by Jackson et al. (US 5,578,641) and Andre et al. (US 5,709,864). Further, Bombardelli et al. (US 5,679,358) teach that adenylate cyclase stimulators such as forskolin reduce the deposits of superfluous fat (see abstract), but Jackson et al. teach that phytosphingosine increases the level of the lipid materials in the stratum corneum in the skin (see column 1, lines 5-10 and column 3, lines 40-43). Nevertheless, the specific combination is not taught to provide a "slimming effect".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-35, 40-44 and 84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising phytosphingosine and an extract of Coleus forskohlii both in a concentration of from 0.001% and 1% by weight to provide a slimming effect on the human body, does not reasonably provide enablement for phytosphingosine alone or in combination with any

lipolytic agent to provide a slimming effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of cosmetic care for obtaining a slimming effect on the human body, comprising the topical delivery on the part or parts of the body presenting subcutaneous fat and in need of said slimming effect of a slimming effective amount of at least one phytosphingosine compound selected from the group consisting of phytosphingosine. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 31 is drawn to "a method of cosmetic care for obtaining a slimming effect on the human body, comprising the topical delivery on the part or parts of the

body presenting subcutaneous fat and in need of said slimming effect of a slimming effective amount of at least one phytosphingosine compound selected from the group consisting of phytosphingosine, its cosmetically acceptable salts and mixtures thereof." Claim 35 is drawn to "wherein said composition further comprises at least one cosmetically acceptable lipolytic agent." Claim 40 is drawn to "wherein said lipolytic agent is an adenylate cyclase enzyme activating agent." Claim 41 is drawn to "the method according to claim 40, wherein said adenylate cyclase enzyme activating agent is selected from the group consisting of forskolin and plant extracts containing the same." Claim 43 is drawn to "the method according to claim 41, wherein said adenylate cyclase enzyme activating agent is selected from the group consisting of extracts of Coleus forskohlii and Plectranthus barbatus."

(2) The breadth of the claims:

Claims 31-35, 40-44 and 84 embrace and read on providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent. The specification does not enable phytosphingosine alone or the combination with any lipolytic agent to provide a slimming effect.

(3) The state of the prior art:

The state of the art regarding effectively providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent is very low. Bombardelli et al. (US 5,679,358) teach that compositions comprising andenylate cyclase stimulators such as forskolin or *Salvia miltiorrhiza* diterpenes and/or with phosphodiesterase inhibitors, such as apigenine-skeleton dimeric flavones reduce the deposits of superfluous fat of any origin (see abstract). On the contrary, Jackson et al. teach that phytosphingosine enhances the formation of ceramides (see column 3, lines 40-43), which increases the level of lipid material in the stratum corneum of the skin (see column 1, lines 5-10). Therefore, all lipoytic agents are not shown to provide a slimming effect. Further, it would seem that the two claimed materials work opposite from each other. Particularly, forsklin reduce deposits of fat whereas phytophingosine increases the level of fat. Thus, the combination of the two would not be expected to provide a slimming effect.

(4) The predictability or unpredictability of the art:

The predictability of providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent is relatively low. Therefore, to one skilled in the art, providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent is unpredictable.

(5) The relative skill of those in the art:

The relative skill in the art is fairly high, with the typical practitioner having a medical degree and/or an advanced degree in the biochemical, chemistry or cosmetic/pharmaceutical-related arts, as evidenced by Bombardelli et al. and Jackson et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that provide a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. Particularly, the specification teaches that *in vitro* tests of phytophingosine or its hydrochloride salt increased the secretion of leptin and adipose cells. The specification teaches that phytosphingosine is thus capable of playing an important role in the control of the stability of the fatty mass (see page 12 in its entirety). Further, phytosphingosine (PS) is capable of stimulating the secretion of leptin did not inhibit the massive action of the extracts of *Coleus* (PB) to decrease lipids (see column 18, lines 3-5). The combination of an extract of Coleus

andphytosphingosine lead to a massive and visible decrease in lipid droplets which are less numerous and of smaller size (see page 20, figure 6).

(7) The quantity of experimentation necessary:

The instant claims read on providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent. As discussed above the specification fails to provide any support for providing a slimming effect on the human body with a composition comprising only phytosphingosine alone or in combination with any lipolytic agent. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation.

Particularly, the skilled practitioner would have to test each and every lipolytic agent in combination with phytosphinogosine, or at least a subset of lipolytic agents that is sufficiently representative, to determine its slimming effect. It is not clear nor is it taught in the prior art that every lipolyic agent has the same “massive action of the extracts of *Coleus* (PB) to decrease lipids” (see specification, column 18, lines 3-5). Thus, if the lipolytic agent does not have the massive action of decreasing lipids, there is a possibility that phytosphinogosine can inhibit its properties being that prior art teaches that it increases lipids. Thus, the skilled artisan would have to undergo exhaustive studies to evaluate each lipolytic agent and its amounts that when combined with phytosphingosine decrease lipids and therefore give a "slimming effect", in order to

be able to fully carry out the invention commensurate in scope with the claims.

Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for obtaining a slimming effect on a part of the human body with a composition comprising phytosphingosine and an extract of Coleus forskohlii both in a concentration of from 0.001% and 1% by weight, but not for providing a slimming effect with a composition comprising phytosphingosine alone or in combination with any lipolytic agent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617